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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/613,177 | 07/10/00 | SAMPATH | K 00960-540 |

PATENT ADMINISTRATOR
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HM12/0105

EXAMINER

FREDMAN, J

ART UNIT

PAPER NUMBER

1655

2

DATE MAILED:

01/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/613,177

Applicant(s)

Sampath et al

Examiner

Jeffrey Fredman

Group Art Unit

1655



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-42 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-42 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1655

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-13, 15, 30-36, drawn to methods of screening for morphogen compounds, classified in class 436, subclass 501.
 - II. Claim 14, 16-23, drawn to compounds, classified in class 532, subclass 1.
 - III. Claims 24, 25, 29, drawn to nucleic acids, classified in class 536, subclass 23.1.
 - IV. Claims 26-28, drawn to proteins, classified in class 530, subclass 350.
 - V. Claims 37-42, drawn to tissue treatment methods, classified in class 424, subclasses 9.1 and 184.1.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions in Group I and in Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the products of Group II can be made by the screening method of Group I, or by chemical synthesis of the constituents.
4. Inventions in Group III and IV and in Group I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

Art Unit: 1655

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of Group I utilizes the nucleic acids of Group III or proteins of Group IV in the screening assay. The process can utilize a variety of other constituents for screening, including a variety of other nucleic acids. Further, the products can be used in many other assays ranging from detection and PCR amplification methods to gene therapy and antisense methods and including nucleic acid purification or expression methods. Similarly, the proteins of Group IV can be used in many other different assays including purification assays, antibody synthesis methods or treatment methods.

5. Inventions in Group I and in Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the method of Group I is involved in screening for compounds and the methods and mode of operation of this method differ in function and effect from the treatment method of Group V, which is involved in using compounds to assay tissues.

6. Inventions in Groups II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Here, the compounds of Group II are structurally and chemically distinct from the nucleic acids of Group III or the proteins of Group IV. Similarly, the nucleic acids of Group III are structurally and

Art Unit: 1655

chemically distinct from the proteins of Group IV. These compounds each have different modes of operation, different chemical functions and different effects.

7. Inventions in Groups II, III, and IV and in Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products of Groups II, III and IV can be used in many other assays. The Group II compounds can be used in screening assays or in treatment assays. The Group III DNA reagents can be used in methods ranging from detection and PCR amplification methods to gene therapy and antisense methods and including nucleic acid purification or expression methods. Similarly, the proteins of Group IV can be used in many other different assays including purification assays, antibody synthesis methods or treatment methods.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9. A telephone call was made to Ivor Elrifi on January 2, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Art Unit: 1655

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff Fredman, Ph.D. whose telephone number is (703) 308-6568.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).


Jeffrey Fredman
Primary Patent Examiner
Art Unit 1655